IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	09/852,547
Confirmation No.:	6474
First-Named Inventor:	David A. Sirbasku
Filing Date:	May 10, 2001
Group Art Unit:	1643
Examiner:	Karen A. Canella
Attorney Docket No.:	057041-000004

Title: COMPOSITIONS AND METHODS FOR THE DIAGNOSIS, TREATMENT AND PREVENTION OF STEROID HORMONE RESPONSIVE CANCERS

DECLARATION OF DAVID A. SIRBASKU UNDER 37 C.F.R. § 1.132

1. My name is David A. Sirbasku, and I am over 18 years of age. I have personal knowledge of all facts I state in this Declaration, unless specifically indicated as being "on information and belief."

2. I am currently the President and CEO of Signe BioPharma, and have been since 2005. The discovery base of this USPTO application was made by me during my tenure at The University of Texas Health Science Center at Houston, Texas. I was one of the founding faculty members of The University of Texas Medical School at Houston and served there for thirty years as a Professor of Biochemistry and Molecular Biology. In recognition of my early growth factor research, I was awarded a five year Faculty Research Award by the American Cancer Society. As a Principal Investigator, I received peer reviewed grants for 28 of 30 years at The University of Texas. These were awarded from the National Cancer Institute,

the American Cancer Society, the U.S. Army Breast Cancer Research Program, the Clayton Foundation, the Susan G. Komen Breast Cancer Foundation, and numerous other private foundations and philanthropic organizations. I have also served as a full term Member and Chairman of grant review committees for the American Cancer Society, National Cancer Institute, National Institutes of Health and the U.S. Army Breast Cancer Research Program. I was honored by appointment to the United States National Board of Medical Examiners.

My other experience pertinent to this USPTO application has been as co-editor of well recognized book series, including a best-known four volume series on serum-free cell culture methods, a two volume series of the Cold Spring Harbor Conferences on Cell Proliferation (Serum-free Cell Growth), and two volumes of Methods in Enzymology entitled Growth Factors. These volumes deal with cell culture assays, appropriate controls and management of the media components. Beyond these, I am a coauthor of more than 140 scientific publications. My earlier work led to national and international recognition including numerous invitations to speak at U.S., European and Asian scientific conferences. This work, plus my more recent discovery of the role of the secretory immune system in mucosal cancer, is the fundamental scientific basis of the intellectual property portfolio before the USPTO and is the basis for founding Signe BioPharma Inc, where I now serve full time.

3. This Declaration is being submitted to provide evidence to rebut allegations of lack of written descriptions made in connection with this application. I have read the above-identified US Patent Application, the rejections provided by the

Examiner and the Response to Office Action that will be filed. I am the inventor of the invention disclosed and claimed therein. I have reviewed the claims that are pending in this application, and I understand that they have been rejected as allegedly lacking written description to support the use of control samples for comparison.

4. It is my view that the use of a control sample or negative control sample, where a material is not added to a sample to compare to a sample where a material is added, is routinely carried out in the biochemical art. This type of testing, utilizing a control sample or negative control sample, is expected to be done when assessing affects of a material on a cell culture whether or not the control sample was explicitly described in a procedure.

5. It is my view that an explicit description of such a control sample, where a material is not added to a cell culture, is not needed, because it is well recognized in the biochemical art that such a control sample will be used to assess an affect on the cell culture of the material, and describing the preparation and use of the sample is implied when carrying out such an assessment.

6. It is my view that those in the art would recognize samples or cell cultures where no substance of interest is added as a control sample or negative control sample used to assess the affect of the substance of interest when added to additional cell cultures. The control sample provides a baseline to compare against another sample that contains the substance of interest. This type of comparison is routinely carried out in the biochemical art, and a description explicitly describing in detail the control sample is not necessary.

7. It is my view that controls are added to each type of assay to identify possible alternate reasons for either negative or positive results. Controls may be different for each type of test sample and therefore must be considered individually to ensure valid results. These are common knowledge facts that do not need reiteration in experimental procedures.

8. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 28 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

David A. Sirbasku

April 6, 2009
Date

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